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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------------------|-------------|----------------------|---------------------|------------------|
| 10/536,935 | 02/15/2006 | Kappei Tsukahara | 082368-004400US | 6397 |
| 20350 | 7590 | 01/25/2008 | EXAMINER | |
| TOWNSEND AND TOWNSEND AND CREW, LLP | | | ARCHIE, NINA | |
| TWO EMBARCADERO CENTER | | | ART UNIT | PAPER NUMBER |
| EIGHTH FLOOR | | | 1645 | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/536,935 | TSUKAHARA ET AL. |
| | Examiner | Art Unit |
| | Nina A. Archie | 1645 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 20 May 2005.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-8 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-8 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :2/15/2006, 9/26/2006, 2/22/2007.

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

2. The drawings in this application have been accepted. No further action by Applicant is required.

Specification

3. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors such as misspelled word cheep on pg. 9. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

4. The disclosure is objected to because of the following informalities: Claim 1 recites the phrase "IV" which is not specifically defined in the specification. Appropriate correction is required.

Claims 4-9 are objected to under 37 CFR 1.75(c) as being in improper form because the claims are dependent from a multiple dependent claim. See MPEP § 608.01(n). Accordingly, claims 4-9 have not been further treated on the merits and are withdrawn from consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

5. As to claim 3 a dependent claim, recites the phrase "affordable value". However, neither the claim nor the specification clearly defines nor sets forth the meaning or means to assess "affordable value". "Affordable value" has no art defined meaning with respect to a filter. Therefore, the skilled artisan would not be readily apprised of the metes and bounds of "affordable value" nor how to assess such. It is unclear how to interpret something and inasmuch as it is not a recognized term and not defined in the specification.

Claim Rejections - 35 USC § 102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant

for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1 and 3 rejected under 35 U.S.C. 102(e) as being anticipated by Walker et al. US Application 20040186407 Date September 23, 2004 Date Filed March 17, 2003.

Claim 1 is drawn to an IV filter that traps myoglobin from venous blood in cases of rhabdomyolysis due to acute causes (e.g. acute limb ischemia, Neuroleptic malignant syndrome, and traumas), being introduced to the venous circulation percutaneously through the internal jugular vein (or any other suitable vein).

Walker et al teach a filter that traps myoglobin from venous blood (see [0066]).

Regarding the recitation of "cases of rhabdomyolysis due to acute causes (e.g. acute limb ischemia, Neuroleptic malignant syndrome, and traumas), being introduced to the venous circulation percutaneously through the internal jugular vein (or any other suitable vein)", said recitation is considered an intended use and thus is given no patentable weight on the IV filter. Therefore the claims are drawn to an IV filter.

Regarding the recitation of "the filter according to claims 1, 2 wherein the filter is left in the vein to trap the myoglobin molecules until the filter is saturated or until the myoglobin saturation in blood is reduced to an affordable value, then the filter is removed" is considered an intended use and thus is given no patentable weight on the IV filter. Therefore the claims are drawn to an IV filter.

7. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al. US Application 20040186407 Date September 23, 2004 Date Filed March 17, 2003 in view of Cordone et al US Patent 5,573,957 Date November 12, 1996.

Claim 1 is drawn to an IV filter that traps myoglobin from venous blood in cases of rhabdomyolysis due to acute causes (e.g. acute limb ischemia, Neuroleptic malignant syndrome, and traumas), being introduced to the venous circulation percutaneously through the internal jugular vein (or any other suitable vein).

Walker et al is relied upon as set forth supra. However Walker et al does not teach a filter which is coated with antimyoglobin antibodies of any suitable type.

Cordone et al teach monoclonal antibody to human cardiac myoglobin. Cordon et al teach antibody bound to a porous membrane or filter. Cordone et al teach that monoclonal antibody absorbs myoglobin and its high affinity for myoglobin.

It would have been *prima facie* obvious at the time the invention was made to produce a filter taught by Walker et al and to incorporate antimyoglobin antibodies coated on the filter as taught Cordone et al because Cordone et al teach antimyoglobin antibody bound to a filter because antibody absorbs myoglobin and it's high affinity for myoglobin.

Status of the Claims

8. No claims are allowed.

Claims 1-3 are rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-0898. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Shanon Foley can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Nina A Archie

Examiner

GAU 1645

REM 3B31



MARK NAVARRO
PRIMARY EXAMINER